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*Patient Care Ombudsman*

**UNITED STATES BANKRUPTCY COURT  
SOUTHERN DISTRICT OF NEW YORK**

In re:

ZHANG MEDICAL P.C., d/b/a  
NEW HOPE FERTILITY CENTER,

Debtor and Debtor-in-Possession

Chapter 11

Case No. 23-10678-PB

**THIRD PATIENT CARE OMBUDSMAN REPORT**

**SUBMITTED December 27, 2023**

**BY:**

**DAVID N. CRAPO, CIPP-US  
PATIENT CARE OMBUDSMAN**

## I. INTRODUCTION

This Report of the Patient Care Ombudsman (“**PCO**”) is issued pursuant to the author’s appointment on June 1, 2023 as the PCO by the United States Trustee for Region (“**U.S. Trustee**”) for debtor Zhang Medical Center, d/b/a New Hope Fertility Center (“**Debtor**”). The appointment arises under section 333 of the United States Bankruptcy Code (11 U.S.C. §§ 101, *et seq.*), which provides for the appointment of a patient care ombudsman “to monitor the quality of patient care and to represent the interests of the patients of the health care business.” The Debtor’s operations constitute “health care businesses” for purposes of the Bankruptcy Code. *See* 11 U.S.C. §101(27A). This report covers the period from October 28, 2023 through December 27, 2023.

Preparation of the PCO’s initial report was hampered and significantly delayed by two factors. The Debtor had not yet provided much of the information requested by the PCO. Additionally, the Food & Drug Administration (“**FDA**”) had only recently finalized a report on the Debtor’s correction of certain deficiencies the FDA found in a 2021 inspection and in two 2023 inspections. Following the filing of the PCO’s initial Patient Care Ombudsman Report on September 13, 2023, the Debtor, with the significant prodding of its attorneys, provided the PCO with virtually all of the information and documentation he had requested. Similarly, in response to a FOIA request submitted on August 24, 2023, on September 26, 2023, the FDA provided the PCO with the documents comprising its final report. The PCO filed his Second Patient Care Ombudsman Report (“**Second Report**”) on October 27, 2023.

## II. ADDITIONAL INFORMATION PROVIDED TO THE PCO.

Since the filing of the PCO’s Second Report, the Debtor has provided the PCO with copies of: (i) its file concerning the September 22, 2023 accreditation inspection of its facility by the College of American Pathologists (“**CAP**”); and (ii) the December 11, 2023 Clinical Laboratory Improvement Amendments (“**CLIA**”) accreditation inspection of the Debtor’s premises. During the same period, Second Report, the New York Department of Health (“**NYDOH**”) provided the PCO with a copy of its file on its inspection of the Debtor’s facility on August 8-9, 2022. The Debtor’s Chief Restructuring Officer, Charles Persing provided the PCO with information concerning the Debtor’s malpractice liability coverage and claims against the Debtor’s malpractice policies.

The PCO’s investigation has not uncovered evidence of sentinel events occurring after October 27, 2023. There is similarly no indication that patients have suffered infections after October 27, 2023 as a result of the clinical treatment they received the Debtor’s facility. Under the circumstances, the information described above that has been provided by the Debtor supports the CPO’s preliminary conclusion that the quality of patient care and safety at the Debtor’s facility are not being compromised.

The PCO has also learned that the Debtor and an equipment lessor have reached a deal concerning rental payments on the subject equipment, which the Debtor uses in providing services to its patients.

### **III. CLIA INVESTIGATION OF THE DEBTOR**

On December 11, 2023, Kathleen Kimball of the NYDOH conducted a CLIA investigation of the Debtor's facility. Dr. Kimball inspected all of the Debtor's Andrology/Endocrinology documents, including lab policies and procedures, quality control records, personnel records and necessary forms. She toured the Andrology/Endocrinology stations. Dr. Kimball found no deficiencies in the Debtor's or the Debtor's operation thereof. Accordingly, the Debtor passed the inspection.

### **IV. NYDOH INVESTIGATION OF THE DEBTOR**

On August 8-9, 2022, one or more representatives of the NYDOH's Tissue Resources Program conducted an onsite audit of the tissue banking activities performed at the Debtor's facility. The audit uncovered deficiencies similar to those previously discovered by the FDA audit, which had previously been reviewed by the PCO. Before preparing the Second Report, the PCO had concluded from his review of the Debtor's files on the NYDOH investigation that the concerns raised by the NYDOH in its investigation had been resolved.

After the filing of the Second Report, NYDOH provided the PCO with a copy of its file on the investigation of the Debtor's facility. Most of the documents in the NYDOH file had been included in the Debtor's files, although the NYDOH's file contained internal work papers. The PCO's review of the NYDOH file confirmed the conclusion he had reached as a result of his review of the Debtor's file that NYDOH's concerns had been resolved.

### **V. CAP INVESTIGATION OF THE DEBTOR**

On September 22, 2023, CAP conducted an accreditation inspection of the Debtor's facility. The inspection team noted certain deficiencies that were easily resolved through corrective actions on the part of the Debtor. As a result of the inspection, the Debtor's labs received their CAP accreditation.

### **VI. LITIGATION AGAINST THE DEBTOR AND ITS CLINICAL EMPLOYEES**

In connection his initial Patient Care Ombudsman Report and the Second Report, the PCO reviewed four litigation matters (three pending and one discontinued) concerning the Debtor and/or members of its medical staff. In none of those matters have any findings been made by a court. Nor have any judgments been entered or any settlements paid. Those matters involve allegations against the Debtor and/or members of its medical staff that have yet to be proved. Moreover, those matters do not present a pattern of negligence or malpractice; each plaintiff alleges a different type of injury. Additionally, the plaintiffs' complaints arise out of actions occurring long before the bankruptcy filing. Under the circumstances, therefore, the existence of those four legal actions do not indicate the compromise of the quality of patient care and safety at the Debtor's facility.

Since the filing of the Second Report, the PCO has learned of three additional complaints against the Debtor.<sup>1</sup> One complaint alleges negligence in the IVF procedure, resulting in the destruction

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<sup>1</sup> A fourth complaint, involving access to medical records, has been resolved.

of embryos in January 2017. A second complaint alleges unauthorized use of the plaintiff's sperm in an IVF procedure. A third complaint alleges negligent IVF transfer, biopsies and genetic testing. As was the case with the four complaints the PCO previously reviewed, the actions complained of in the three complaints more recently reviewed by the PCO occurred before July 1, 2019, long before the audits of the Debtor's premises by the FDA and the NYDOH and the commencement of the corrective actions undertaken by the Debtor in response to the inspections. No judgments have been entered against the Debtor on those complaints and no judicial findings have been made. No insurance proceeds have been paid to the plaintiffs. Nevertheless, the PCO awaits receipt from the of more specific information about those cases.

Citing the Debtor's bankruptcy filing and the complaints described above, the Debtor's current professional liability carrier has advised that it will not renew the Debtor's coverage when it expires on March 1, 2024. The Debtor has advised the PCO of its efforts to obtain new professional liability coverage.

## **VII. ADDITIONAL CONSIDERATIONS**

As noted above, the PCO has not uncovered any current deficiencies in the actual performance of the fertility-related procedures the Debtor provides. The information available to the PCO does not indicate that the Debtor has had to dismiss employees for deficiencies related to patient care or safety during 2023. There is no evidence of a failure in infection control at the Debtor's facility. No evidence exists of falls or other injuries at the Debtor's facility. The staff is competent and, based on the PCO's inspection of the Debtor's facility, attentive to the Debtor's patients. The Debtor has maintained CLIA accreditation and obtained CAP accreditation. There is no indication of any problems with violence at the facilities. It also bears noting that the neither the FDA nor the NYDOH pointed out any deficiencies in compliance with applicable regulations occurring after July 19, 2022. In that regard, it is noted that the FDA conducted onsite investigations at the Debtor's facility in February and April of this year. Under the circumstances, it appears that the investigations of the Debtor by the FDA and the NYDOH, together with the CLIA and CAP inspections, have had the desired effect of inducing compliance with applicable regulations.

## **VIII. FINDINGS**

Based on his review of the publicly available information concerning the Debtor, the PCO has made the following findings:

- Finding #1:** The PCO has not received any information indicating that quality of care provided to the Debtor's patients (including patient safety) is not acceptable and is currently declining or is otherwise being materially compromised.
- Finding #2:** In light of the limited amount of any negative information about the Debtor and its clinical staff, the Debtor's resolution of investigations by the FDA and the NYDOH, the oversight and supervision provided by the Debtor's clinical staff appears to sufficient to uncover quality of care deficits if they arose.
- Finding #3:** The PCO's periodic review of public records, receipt of information on the three newer claims against the Debtor, as well as any communications receives from

and after the date of this report from regulatory and accreditation agencies from the Debtor should provide a reasonable basis to monitor whether the quality of care (including patient safety) provided by the Debtor is declining or otherwise materially compromised.

## **IX. CONCLUSION**

Under the circumstances, the current performance of the Debtor and its existing structures reveals a facility that apparently continues to provide the same level of patient care and safety it historically provided since before the Debtor's bankruptcy filing.

. Respectfully submitted to the Court on December 27, 2023 by:

/s/ David N. Crapo  
David N. Crapo, Esq.  
Patient Care Ombudsman